UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,570	01/23/2004	Pamela M. Drake	340082.401	4880

500 7590 09/21/2005

SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 6300
SEATTLE, WA 98104-7092

EXAMINER	
BARNHART, LORA ELIZABETH	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/763,570	DRAKE ET AL.	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,7 and 11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,7 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/23/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment received 7/27/05 canceling claims 3, 6, 9, 10, and 12-26 is noted.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-8 and 11, in the reply filed on 7/27/05 is acknowledged. Applicant's election without traverse of the species (c) a composition comprising six specific bacteria and (r) fructooligosaccharides in the same reply is acknowledged. Claim 8 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Examination will continue at this point on claims 1, 2, 4, 5, 7, and 11 only, as they pertain to the elected species.

Specification

The abstract of the disclosure is objected to because it does not describe the invention completely. Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper content, language, and format of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and **should include that which is new in the art to which the invention pertains**. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
(3) if a chemical compound, its identity and use;
(4) if a mixture, its ingredients;
(5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of **50 to 150 words**. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. **The form and legal phraseology often used in patent claims, such as "means", and "said," should be avoided.** The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The disclosure is objected to because of the following informalities: It recites, for example, "Lactobacillus acidophilus," which is not formatted in an art-accepted manner. Scientific (Latin) genus and species names should be italicized, with only the first letter of the genus name capitalized, i.e. *Lactobacillus acidophilus*. The entire specification should be reviewed and corrected.

The use of the trademark "DDS 1" has been noted in this application (page 9, lines 5-6). It should be capitalized wherever it appears and be accompanied by the generic terminology. The trademarks at page 16, line 1, should be corrected in the same way. Although the use of trademarks is

permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

Claim 7 is objected to because of the following informalities: It recites "Lactobacillus acidophilus," which is not formatted in an art-accepted manner. Scientific (Latin) genus and species names should be italicized, with only the first letter of the genus name capitalized, i.e. *Lactobacillus acidophilus*. The spelling of the bacterial species and genuses should be verified; the words "*thermophilus*" and "*Bifidophilus*" are currently misspelled at line 2. The words "spirulina" and "chlorophyllins" are misspelled at line 4.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 5, 7, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "a bacteria nutrient", which is confusing. It is not clear whether this phrase refers to a nutrient for bacteria; to a nutrient produced by bacteria; or to bacteria that are nutrients for some unnamed consumer. Clarification is required.

Because claims 2, 5, and 11 depend from indefinite claim 1 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

Claim 7 is confusing because it recites the species "*Bifidophilus longum*" and "*Bifidobacteria bifidus*", neither of which is an art-accepted term. See reference U (entries from the ATCC bacterial database). Clarification is required. In the interest of compact prosecution, these terms have been interpreted as meaning "*Bifidobacterium longum*" and "*Bifidobacterium bifidum*", respectively.

Claim 11 is confusing in that it requires that the bacteria be "prepared by filtration". It is not clear what is being filtered. Clarification is required. In the interest of compact prosecution, the examiner has interpreted the phrase "prepared by filtration" as meaning "separated from their liquid growth media by filtration."

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The standard for patentability in the area of living organisms and biomolecules is whether the claimed matter "is the result of human intervention." See M.P.E.P. § 2105. Claim 1 is currently broadly drawn to a composition comprising bacteria, a bacteria nutrient, and an antimicrobial agent; the claim therefore reads on Chinese soil comprising *Actinoplanes*

tsinanensis. *A. tsinanensis*, which is a soil bacterium native to China, naturally produces chuangxinmycin, which is toxic to at least *E. coli* and *S. dysenteriae* (see reference V). Claim 1 also reads on a person who has been infected with bacteria and is taking antibiotics to fight the infection. Applicant should note in particular that the claim does not currently require that the bacteria be isolated or present as a biologically pure sample.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Gatto et al. (1998, *Journal of Biological Chemistry* 273: 10578-10585; reference W). The claim is drawn to a composition comprising bacteria, a bacteria nutrient (which, in this case, has been interpreted as meaning, "a nutrient for bacteria"), and an antimicrobial agent. Gatto et al. teach *E. coli* cells growing on LB nutrient agar that comprises kanamycin (page 10579).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which

> said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4, 5, 7, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farmer (2003, U.S. Patent 6,645,506; reference A). The claims are drawn to a composition comprising bacteria, a bacterial nutrient (which, in this case, has been interpreted as a nutrient made by bacteria), and an antimicrobial agent. In some dependent claims, the antimicrobial agent is antifungal, in particular nystatin. In some dependent claims, the nutrient is a

fructooligosaccharide (FOS). In some dependent claims, the bacteria are a specific mixture of six bacterial species and are prepared via filtration from their culture media.

Farmer teaches therapeutic compositions comprising *Bacillus coagulans* and fructooligosaccharide (column 25, line 57, through column 26, line 25; "Formulation 1"). Farmer teaches that said composition may also comprise one or more of numerous probiotic bacteria (column 21, line 63, through column 22, line 27). Farmer teaches that the composition may further comprise an antimicrobial agent, for example an anti-fungal compound such as nystatin (column 22, lines 28-51, especially line 45).

The selection of probiotic bacteria to be included in the composition of Farmer clearly would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that Farmer teaches that the bacteria may be one or more of any of numerous probiotic bacteria and that the recited bacteria are art-accepted equivalents column 2, lines 21-32). A holding of obviousness over the cited claims is therefore clearly required. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

While Farmer does not explicitly teach a composition comprising a mixture of probiotic bacteria, the inclusion of multiple different strains (as required in instant claim 7) does not render the instant composition patentable. Farmer specifically contemplates compositions comprising multiple strains (column 2,

lines 19-22). In addition, it is well established that duplicating components with similar functions within a composition is obvious; see *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960) and M.P.E.P. § 2144.04.

Claim 11 is a product-by-process claim. M.P.E.P. § 2113 reads, "Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps." As such, the requirement that the bacteria be prepared by filtration has been considered only to the extent that it affects the structural properties of the bacteria resulting from said preparation. In any case, Farmer teaches preparing bacteria by filtration (column 14, lines 50-57).

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)

The use of 35 U.S.C. §§ 102 and 103 rejections for product-by-process claims has been approved by the courts. "[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

A person of ordinary skill in the art would have had a reasonable expectation of success in including nystatin in the composition of Farmer because Farmer specifically contemplates such an addition; at column 21, lines 55-62, Farmer suggests a composition comprising probiotic bacteria and an anti-fungal compound. The skilled artisan would have been motivated to include nystatin in the composition of Farmer for the expected benefit that fungal infections might be prevented by the administration of said composition.

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute one or more of the bacteria at

columns 21-22 into the exemplified composition of Farmer because Farmer teaches that the bacteria are art-accepted substitutes. It would have been further obvious for the artisan to add nystatin to the composition of Farmer because Farmer teaches that the inclusion of antifungals in bacterial compositions retards the growth of yeast and molds (column 5, line 62, through column 6, line 12).

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Claims 1, 2, 5, and 11 are also rejected under 35 U.S.C. 103(a) as being unpatentable over van Lengerich et al. (2001, U.S. Patent 6,190,591; reference B). The claims are drawn to a composition comprising bacteria, a nutrient made by bacteria, and an antimicrobial agent. In some dependent claims, the antimicrobial agent is antifungal. In some dependent claims, the bacteria are produced by filtration.

van Lengerich et al. teach a controlled-release capsule comprising a pharmaceutical component (Examples 1-9). van Lengerich et al. teach that the composition may comprise any of numerous compounds produced by bacteria (including penicillin; column 12, line 2) and any of numerous antifungal agents (including nystatin; column 11, line 60). van Lengerich et al. further teach that the composition may comprise probiotic bacteria (column 9, lines 34-42).

A person of ordinary skill in the art would have had a reasonable expectation of success in adding probiotic bacteria, compounds produced by bacteria, or antifungal agents to the capsules of van Lengerich et al. because van

Lengerich et al. teach that the capsules may comprise any pharmaceutical or therapeutic compound (column 9, lines 19-32). The skilled artisan would have been motivated to include bacteria, bacterial compounds, and antifungals for the expected benefit that upon administration, the capsules would deliver mold-free bacteria to the digestive system.

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to add bacteria, bacterial compounds, or antifungals to the capsules of van Lengerich et al. because van Lengerich et al. teach that any or all of these may be incorporated into said capsules.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

No claims are allowed. No claims are free of the art.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is

571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lora E Barnhart

leb

SANDRA E. SAUCIER
PRIMARY EXAMINER